Filed for intro on 02/13/2003
HOUSE BILL 200 By
Turner M

SENATE BILL 1072
By Jackson

AN ACT to amend Tennessee Code Annotated, Title 53; Title 56; Title 63; Title 68 and Title 71, relative to the "Tennessee Fair Market Drug Pricing Act".

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. This act shall be called the “Tennessee Fair Market Drug Pricing Act.”

SECTION 2.

(a) The general assembly finds that:

(1) The state of Tennessee pays substantially more than the fair market price for many prescription drugs used in the Medicaid program. Considering the large volume of drugs purchased, the state will receive better drug prices by entering into voluntary negotiations with drug companies for supplemental rebates above and beyond the federally designated rebates.

(2) A number of states, including California, Florida, Illinois, Louisiana and Michigan, currently have programs to negotiate supplemental rebates. As a result, those states receive better Medicaid drug prices than Tennessee.

(3) In this time of economic difficulty, Tennessee needs to maximize its financial resources in order to provide as much health coverage as possible for low-income residents. Now more than ever, Tennessee needs to lower the prices it pays for prescription drugs.

(4) At the same time, approximately one in four Tennessee residents are uninsured or underinsured for prescription drug coverage, and do not qualify for Medicaid. These uninsured or underinsured residents pay excessive prices for prescription drugs. In many cases, these excessive drug prices have the effect of denying residents access to medically necessary care, thereby threatening their health and safety.

(5) Among these uninsured and underinsured residents, many require repeated doctor or medical clinic appointments, having grown sicker because they cannot afford to take the drugs prescribed for them. Many are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them that could have avoided the need for hospitalization. Many others enter expensive institutional care settings because they cannot afford the prescription drugs that could have supported them outside of an institution. In each of these circumstances, uninsured and underinsured residents too often become Medicaid recipients because of their inability to afford prescription drugs. Therefore, helping secure lower drug prices for the uninsured and underinsured directly benefits and supports Medicaid.

(6) The state government is the only agent that, as a practical matter, can play an effective role as a market participant on behalf of all residents who are uninsured, underinsured or are Medicaid beneficiaries. The state already provides drugs and acts as a prescription benefits

manager for a variety of programs, and should expand that role to negotiate voluntary drug rebates, using these funds to maintain and expand Medicaid services while offering lower drug prices to the uninsured who do not qualify for Medicaid.

(b) Recognizing that the state already acts as a prescription benefits manager for a variety of health plans and assistance programs, this law is enacted to cover new populations by expanding the state's role as a participant in the prescription drug marketplace, negotiating voluntary rebates from drug companies, and using the funds to make prescription drugs more affordable to the state Medicaid program and to state residents. Such a program will improve public health and welfare, promote the economic strength of our society, and both directly and indirectly benefit the state Medicaid program.

SECTION 3. Tennessee Code Annotated, Title 68, Chapter 1, Part 1, is amended by adding the following new section:

Section 68-1-120.

(a) As used in this section:

(1) "Commissioner" means the commissioner of the department of health, or the commissioner's designee or designees.

(2) "Department" means the department of health.

(3) "Manufacturer" means a manufacturer of prescription drugs as defined in 42 U.S.C. Section 1396r-8(k)(5), including a subsidiary or affiliate of a manufacturer.

(4) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale, and that has a labeler code from the food and drug administration under 21 Code of Federal Regulations, 207.20 (1999).

(5) “Participating retail pharmacy” means a retail pharmacy or other business licensed to dispense prescription drugs in this state that participates in the state Medicaid program or voluntarily agrees to participate in the Rx Card program.

(6) “Wholesaler” means a business that lawfully distributes prescription drugs in this state.

(b)

(1) The commissioner shall negotiate discount prices or rebates for prescription drugs from drug manufacturers and labelers. A drug manufacturer or labeler that sells prescription drugs in this state may voluntarily elect to negotiate:

(A) supplemental rebates for the Medicaid program over and above those required under 42 U.S.C. Section 1396r-8,

(B) discount prices or rebates for the Rx Card program, and

(C) discount prices or rebates for any other state program that pays for or acquires prescription drugs.

(2) In negotiating rebate terms, the commissioner shall take into consideration: the rebate calculated under the Medicaid rebate program pursuant to 42 U.S.C. Section 1396r-8, the price provided to eligible entities under 42 U.S.C. Section 256b, and any other available information on prescription drug prices, discounts and rebates.

(3)

(A) The commissioner shall prompt a review of whether to place a manufacturer’s or labeler’s products on the prior authorization list for the state Medicaid program and take similar

actions involving prior authorization or formularies for any other state-funded or operated prescription drug program, if:

(i) the commissioner and a drug manufacturer or labeler fail to reach agreement on the terms of a supplemental Medicaid rebate or a discount or rebate for the Rx Card program, and

(ii) the discounts or rebates offered by the manufacturer or labeler are not as favorable to the state as the prices provided to eligible entities under 42 U.S.C. Section 256b.

(B) Any prior authorization must meet the requirements of 42 U.S.C Section 1396r-8(d)(5) and be done in accordance with Section 5 of this act. The commissioner shall promulgate rules creating clear procedures for the implementation of this section.

(C) The names of manufacturers and labelers that do not enter into rebate agreements are public information, and the department shall release this information to the public and actively distribute it to doctors, pharmacists, and other health professionals.

(c)

(1) The department shall establish the Rx Card program as a state pharmaceutical assistance program under 42 U.S.C. Section 1396r-8(c)(1)(C)(i)(III), to provide discounts to participants for drugs covered by a rebate agreement. Using funds from negotiated rebates, the department shall contract with wholesalers and/or participating retail pharmacies to deliver discounted prices to Rx Card participants.

(2) The drug discounts received by Rx Card participants shall be calculated by the commissioner on a quarterly basis. That calculation shall provide discounts approximately equal to the average amount of the negotiated drug rebate minus an amount to cover the reasonable administrative costs of the Rx Card program.

(3)

(A) An individual is eligible to participate in the Rx Card program if such individual is a resident of the state and is not ineligible under item (B).

(B) An individual is ineligible to participate in the Rx Card program if such individual is eligible for assistance under the state's Medicaid program or is covered by an insurance policy that provides benefits for prescription drugs equal to or greater than the benefits provided under the Rx program, as delineated by rules promulgated by the commissioner.

(C) The department shall establish simple procedures for enrolling Rx Card participants and shall undertake outreach efforts to build public awareness of the program and maximize enrollment by eligible residents.

(4)

(A) The commissioner shall adopt rules requiring disclosure by participating retail pharmacies to Rx Card program participants of the amount of savings provided as a result of the Rx Card program. The rules must protect information that is proprietary in nature.

(B) A participating retail pharmacy shall verify to the department the amounts charged to Rx Card participants and non participants, and shall provide the department with utilization data necessary to calculate rebates from manufacturers and labelers. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule or regulation. The department may not impose transaction charges on wholesalers or participating retail pharmacies that submit claims or receive payments under the program.

(C) Wholesalers and/or participating retail pharmacies shall be paid in advance for Rx Card discounts or shall be reimbursed by the department on a weekly basis.

(D) The department may require a wholesaler or participating retail pharmacy to segregate drugs under the Rx Card program from other drug inventory. The department may require a wholesaler or participating retail pharmacy to maintain records of acquisition and disposition of drugs under the Rx Card program separately from the wholesaler's or pharmacy's other records.

(d)

(1) Disputes or discrepancies in rebate amounts must be resolved using the process established in this subsection.

(A) If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually

agreed-upon, independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

(B) If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon, independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the audit, the department shall justify the reason for the discrepancy or provide a refund to the manufacturer or labeler.

(C) Following the procedures established in paragraph (a) or (b), either the department or the manufacturer or labeler may request a hearing. Supporting documentation must accompany the request for a hearing.

(2) The department shall report the enrollment and financial status of the Rx Card program and report savings from supplemental Medicaid rebates to the legislature by February 1 each year.

(3) Where the commissioner finds that it is beneficial to both the Rx Card program and another state program, including the state Medicaid program, to combine drug-pricing negotiations to maximize drug rebates, the commissioner shall do so.

(4) The department shall adopt rules to implement the provisions of this section.

(5) The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this section.

SECTION 4. In addition to the Rx Card program established in Section 3 of this act, the department of health shall seek a Section 1115 Medicaid waiver to establish a pharmacy discount program modeled after the Healthy Maine Prescriptions Program, as approved by the U.S. department of health and human services. If the waiver is approved, the department shall implement that program following consultation with the senate and house finance, ways and means committees.

SECTION 5. Tennessee Code Annotated, Title 71, Chapter 5, Part 1, is amended by adding the following as a new section:

Section 71-5-194.

(a) Beginning January 1, 2004, all manufacturers and labelers of drugs that participate in the medical assistance program under this part shall participate in the drug rebate program under Section 3 of this act.

(b) The department shall adopt rules for the medical assistance program requiring additional authorization for the dispensing of drugs provided from manufacturers and labelers who do not enter into agreements with the department under Section 3 of this act.

(c) With respect to aspects of the medical assistance program operating under a federal waiver for the provisions of services under this part, the provisions of this section shall not take effect unless the federal healthcare financing administration provides any necessary approvals required under the terms of the waiver or applicable federal law.

(d) For the purpose of this section, "labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the

federal food and drug administration under 21 Code of Federal Regulations, Section 207.20.

SECTION 6. The provisions of this act shall be severable, and if any phrase, clause, sentence, or provision is declared to be invalid or is preempted by federal law or regulation, the validity of the remainder of this act shall not be affected.

SECTION 7. This act shall take effect on July 1, 2003, and discounts to participants in the Rx Card program shall begin by January 1, 2004.